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Variables	Men	Women	P value
Age	82.11±8.4	82.88±11.5	0.48
STS score	10.6±4.5	13.03±5.4	0.006
CAD>50%	82.9%	50.0%	0.004
Pre BAV LV EF%	40.7±16.8	49.4±15.2	<0.001
Max. balloon diameter, mm	24.4±1.35	21.9±2.1	<0.001
Mean AV gradient change post BAV, mmHg	21.38±11.40	26.38±14.65	0.01
In hospital stroke	1.5%	1.3%	1.00
VARC minor bleed	3.1%	0	0.04
VARC stage 3 AKI	3.3%	0	0.05
In hospital Death	5.6%	5.3%	0.90
30 day mortality	5.9%	10.6%	0.13
One year mortality	34.2%	28.5%	0.3

VARC Composite Endpoints n = 69	
Device Success	**39**
Successful Delivery/Deployment	4
More than one device implanted	32
Moderate or Severe Prosthetic AR	3
Safety at 30 Days	**21**
Death	9
Stroke	5
Life-Threatening Bleeding	3
Major Vascular Complication	2
Redo Procedure	1
Myocardial Infarction	1
Combined Efficacy	**9**
Mortality > 30 days	5
Valve Dysfunction	4
Non-VARC Events n = 34	
Permanent Pacemaker	17
Rhythm/Conduction Disturbance	8
Other	9

CRT-711

Publicly Reported Adverse Events with the Edwards SAPIEN Valve - Trends and Event Classification in the FDA MAUDE Database

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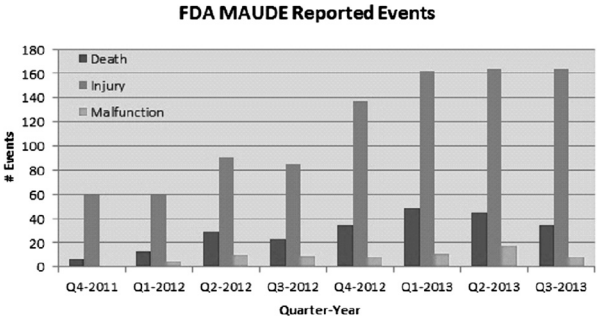
Background: The frequency and significance of adverse events (AE) reported with transcatheter aortic valve replacement (TAVR) using Edwards SAPIEN THV in the voluntary, publicly available MAUDE database has not been characterized.
Methods: The FDA MAUDE Database was queried for all reported events relating to Edwards SAPIEN TAVR through Oct. 2013. Data was reported on a quarterly basis using the MAUDE classification system. AE reports from 10/2011 through 4/2012 were categorized based on the Valve Academic Research Consortium (VARC) classification system.
Results: 1222 total AE reports were found (MAUDE categories: death n=234, injury n=921, malfunction n=67) with a significant increase over the first 5 analyzed quarters with stabilization in the final 3 quarters (fig 1). Of the 103 consecutive AEs analyzed, 69 were classifiable by VARC and 34 were not (table 1).
Conclusion: Despite the limitations of this voluntary database, AE reports have increased since FDA approval of the Edwards SAPIEN THV, but have leveled off in 2013. The utility of the database to assess real-world AEs could be improved by the routine use of an accepted AE classification system.



CRT-712

Predicting the Improvement of Left Ventricular Function in Patients Undergoing Transcatheter Aortic Valve Replacement Using Baseline QRS Duration and Amplitude

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Background: The improvement of the left ventricular ejection fraction (LVEF) in patients with impaired left ventricular function and severe aortic stenosis (AS) after transcatheter aortic valve replacement (TAVR) is highly variable. Prolonged QRS duration (QRSd) and decreased QRS amplitude (QRSa) are associated with impaired left ventricular function. This study is to assess the predictive values of baseline QRSd and QRSa on improvement of LVEF in patients with reduced LVEF and severe AS after TAVR.
Methods: Baseline ECGs and serial echocardiograms of 96 consecutive patients with LVEF < 45% who underwent TAVR using Edwards-SAPIEN (94%) and CoreValve (6%) and survived to hospital discharge between 2007 and 2013 in our hospital were reviewed.
Results: Patients with QRSd≥145ms(n=48) had higher incidence of left bundle branch block (26.2%), permanent right ventricular pacemaker implantation(50%) and lower incidence of intraventricular conduction delay(16.7%) as compared to those with QRS<145ms (7.1% , 4.7% and 50%) respectively. 17(17.7%) patients had low QRSa (<5mm on lime leads or <10mm on precordial leads) with 9(53%) patients with QRS≥145ms. After a mean of 12 ±14months, the patients with ORSd<145ms had a significant increase of LVEF (15.5±3.5%) vs no significant change (4.0 ±4.0%) in those with QRSd≥ 145ms. By Receiver Operating Characteristic analysis, the QRSd of 145ms and normal QRSa were determined as the optimal criteria for predicting the improvement of LVEF after TAVR. The probability of increasing LVEF by at least 10% was 76±13% and 19±12% for patients with QRSd < and ≥ 145 ms respectively. The sensitivity and specificity of using QRSd = 145ms and normal QRSa as predictor for significant increase in LVEF were 80% and 77% respectively. The p-value from the paired t-test of pre- and post-EF for patients with QRSd < and ≥ 145ms was 3.85E-11 and 0.02 respectively.
Conclusion: Among patients with LVEF below 45% and severe AS undergoing TAVR, the baseline QRSd and QRSa accurately predict significant improvement of left ventricular function. A vast majority of the subjects with QRSd < 145ms and normal QRSa have a 10% or more improvement of LVEF after TAVR.